

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 14 FEB 2005

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Applicant's or agent's file reference DURE034 WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US02/28519	International filing date (day/month/year) 06 September 2002 (06.09.2002)	Priority date (day/month/year)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 31/66, 31/553 and US Cl.: 514/119, 211.09		
Applicant DURECT CORPORATION		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>3</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 06 April 2004 (06.04.2004)	Date of completion of this report 19 January 2005 (19.01.2005)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Raymond J Henley III <i>Janice Ford</i> Telephone No. 571-272-1600	

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US02/28519

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☒ the description:  
pages 1-36 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages NONE, as originally filed  
pages 37-39, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:  
pages 1-7, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☐ the sequence listing part of the description:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US02/28519**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims 7-18	YES
	Claims 1-6	NO
Inventive Step (IS)	Claims 7-18	YES
	Claims 1-6	NO
Industrial Applicability (IA)	Claims 1-18	YES
	Claims NONE	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-6 do not meet the criteria under PCT Article 33(2) for novelty because OLNEY (U.S. Patent No. 5,039,528) teaches pharmaceutical compositions comprising the claimed NMDA receptor antagonist. The statements of intended use or function in the claims fail to distinguish the claimed compositions from those of the prior art because such statements fails to impart any physical feature to the claimed compositions that is not found in the prior art composition.

Claims 7-18 meet the criteria under PCT Article 33(2) for novelty because the prior art fails to teach the presently claimed system for delivery of a drug to the round window membrane of the inner ear or method for treating an inner ear disorder.

Claims 1-6 do not meet the criteria under PCT Article 33(3) for inventive step because OLNEY (U.S. Patent No. 5,039,528) teaches pharmaceutical compositions comprising the claimed NMDA receptor antagonist. The statements of intended use or function in the claims fail to distinguish the claimed compositions from those of the prior art because such statements fails to impart any physical feature to the claimed compositions that is not found in the prior art composition.

Claims 7-18 meet the criteria under PCT Article 33(3) for inventive step because the prior art fails to teach or suggest the presently claimed system for delivery of a drug to the round window membrane of the inner ear or method for treating an inner ear disorder.

Claims 1-18 meet the criteria under PCT Article 33(4) because pharmaceutical compositions comprising the claimed NMDA receptor antagonists; system for delivery of a drug to the round window membrane of the inner ear; and method for treating an inner ear disorder would each have applicability in the medical industry.

----- NEW CITATIONS -----

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US02/28519

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61K 31/66, 31/553

US CL :514/119, 211.09

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/119, 211.09

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- A	US 5,039,528 A (OLNEY) 13 August 1991 (13.08.91), see column 8, line 64 - column 9, line 2 and column 13, lines 12-19.	13-14 ----- 1-12 and 15-21

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

"	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"B"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Z"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

12 OCTOBER 2002

Date of mailing of the international search report

19 JUN 2003

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

RAYMOND J. HENLEY III

Telephone No. (703) 308-1235